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EVALUATION OF TISSUE REACTIVITY OF DENAFLEX™ GRAFTS IN RABBIT SUBCUTANEOUS AND INTRAMUSCULAR IMPLANTS

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Denaflex™ is a small diameter biological vascular graft intended for coronary artery bypass application. Source for the Denaflex™ graft is bovine internal thoracic artery, chemically treated with polyepoxy compounds (Denacol®).
In this communication, we evaluated the host cellular reactions to tissue sections of Denaflex™ grafts implanted subcutaneously (SC) and intramuscularly (IM) in rabbits and compared with glutaraldehyde treated bovine carotid arterial tissue (St. Jude's Biopolymeric™ graft) sections implanted in subcutaneously .
The results are summarized as follows:

- There was no histopathologic evidence of chemically induced cytotoxicity at any of the sacrifice intervals for either IM or SC sites.
- At all explant intervals, IM and SC responses were consistent with those expected in non-toxic uncomplicated foreign body reactions.
- Both Denaflex™ and Biopolymeric™ implants induced similar histopathologic changes.

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TIN COATED PACEMAKER LEADS FOR RELIABLE CAPTURE RECOGNITION IN HUMAN HEART

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Capture recognition - i.e. the detection of evoked potentials after a stimulating pulse - is a prerequisite for various safety features of stimulators, such as an internal stimulation threshold measurement and adaptation in order to avoid fatal complications due to electrode displacement. During the past two decades many attempts have been made to pace and to detect the ECG using the same electrode as actuator and sensor, but all trials missed due to a physical phenomenon of the electrode-myocardium interface, the electrode polarisation. Consequently the evoked potential, which occurs within 100 and 300 ms after the stimulation, is usually covered by an after potential of approximately 10 mV even if an autoshort is applied directly after the pulse, resulting in an overload of the sensing amplifiers.

Since electronic measures for a suppression of this after potential were not successful, an electrode with minimized polarization - i.e. with maximized Helmholtz capacity - is required. For this purpose a porous PVD-coating of titanium nitride (TiN) with fractal surface structure was applied to conventional hemispherical tip electrodes. Due to the fractal structure a Helmholtz capacity was achieved more than 1000 times higher than for smooth electrodes, resulting in specific capacities of up to 50 mF per square centimeter of geometric surface area.

Several clinical measurements during temporary stimulation therapy or pacemaker exchange using such a TiN-coated electrode (TIR 60-BP, BIOTRONIK) and an external pacemaker demonstrated, that reliable capture recognition via the pacing electrode can be assured, if electrode polarisation is minimized using a porous coating of TiN. The after potential during the evoked potential was nearly zero in each case.

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BIOCOMPATIBILITY OPTIMIZATION OF PACEMAKER LEADS BY FRACTAL SURFACE STRUCTURING

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During the past three years titanium nitride (TiN) coated pacemaker electrodes have become famous as "low energy electrodes" due to their excellent stimulation and sensing behaviour. However, reported results of different groups are contradictory even for tips of similar geometry and size. Although the same material - reactively sputtered and stoichiometric TiN - was used, the surface structure was different varying from smooth to crystalline and rough. The best clinical results have been found for coatings with fractal surface structure and high active surface area (1000 times larger than the substrate area). These differences lead to the supposition, that the clinical performance of an electrode depends mainly on its surface structure and not or only minor on the material.

In order to prove this assumption, pacemaker tip electrodes of the same hemispherical shape and size (10 mm^2) were coated with TiN (n=345) and Ir (n=45) using the same sputtering process resulting in a reproducible fractal surface structure for both types of coating. Initially the mean value of the threshold voltage (pulse width 0.5 ms) of TiN electrodes in man was 0.24 V increasing during the first four weeks up to a stable value of 0.78 V. Ir coatings exhibited 0.33 V inititally and 0.53 V six months after implantation; the standard deviation was lower than 0.1 V in each case. All R-potentials were well above 15 mV.

In conclusion unipolar pacemaker leads with TiN or Ir coated tips having the same fractal surface structure show significantly lower thresholds and better sensing performance than TiN coated tips with a smoother surface structure as well as smooth Pt/Ir tips. In consequence stimulation performance is essentially determined by the surface structure of the interface. A large active surface results in low impedance and therefore in low threshold voltage thus reducing electrochemical reactions which induce chemical inflammation. Consequently tip coatings with fractal surface structure having the highest active surface in comparison to smoother electrodes show the best functional biocompatibility.

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IN VIVO HEMODYNAMIC EVALUATION OF THE MITRAL VALVES WITH AN IMPLANTED ANNULOPLASTY RING

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With the introduction of advanced valvuloplasty techniques, mitral valve repair for mitral regurgitation with an annuloplasty ring has been increasingly popular in recent years because there still remains no ideal cardiac valve substitute. The purpose of this study was to evaluate the hemodynamic performance of the mitral valves with an implanted flexible Cosgrove Annuloplasty Ring (5 samples) utilizing a sheep model. The semi-flexible standard Carpentier-Edwards® Mitral Annuloplasty Ring (3 samples) which has been satisfactorily used in USA clinics for almost 10 years was employed as a control. Unfortunately, no sheep with severe mitral regurgitation could be found for the study. Therefore, this study was to test the safety of the devices rather than to test the efficacy of the annuloplasty rings. The evaluation was performed, using a non-invasive color Doppler flow mapping system, at various periods post implantation. The two-dimensional tomographic image study showed that the mitral leaflets maintained normal mobility throughout the entire course of the study for both the control and test groups. In addition, no left ventricular outflow tract obstruction due to systolic anterior motion (SAM) of the mitral valve was observed in any of the studied cases. The color Doppler flow mapping study indicated that the implantation of a standard Carpentier-Edwards® ring or a Cosgrove ring did not induce any flow turbulence or flow separation in the vicinity of the mitral valve. The continuous-wave Doppler study evidenced that the transvalvular pressure gradients measured at post-implantation and prior to retrieval were slightly increased for both the control and test groups. Note that the mitral valves of the sheep used in the study were originally not diseased. The increments in both groups were negligible. In conclusion, the results demonstrated that the implantation of a semi-flexible standard Carpentier-Edwards® ring or a flexible Cosgrove ring did not induce any abnormal valve function or blood flow which might be detrimental to the health of the sheep.